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(54) Remotely-activated vertebroplasty injection device

(57) A remotely-activated injection device for use in vertebroplasty is provided to inject a fluorescent probe material into a patient. The injection device includes a pump defining an injection chamber having an exit opening; an actuator; and a cable having a first end cou-

pled to the actuator, and a second end remotely engaging the pump. The actuator remotely controls the pump by responsive movement of the cable to thereby cause injection of a fluorescent probe material from the injection chamber of the pump through the exit opening to the patient.

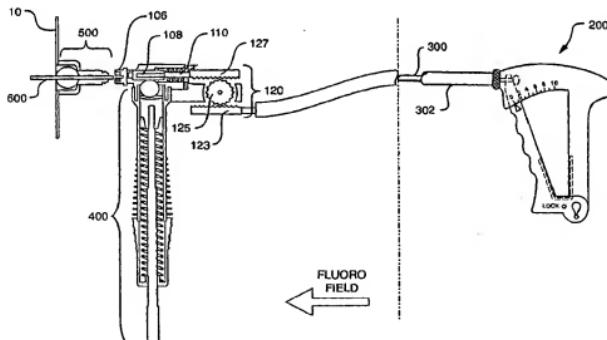


FIG. 3

Description**BACKGROUND OF THE INVENTION**

[0001] Over 700,000 vertebral fractures occur each year in the United States. Eighty-five percent of these vertebral fractures are associated with osteoporosis. Osteoporosis causes bone to lose density and strength resulting in porous, weak bones especially susceptible to fracture.

[0002] Vertebroplasty is a non-surgical procedure for combating the effects of osteoporosis and the like, in which a vertebral body is structurally reinforced using a special cement-like substance, or bone cement. A typical bone cement for use in vertebroplasty is called "polymethylmethacrylate acrylic cement" (PMMA). Vertebroplasty has been used in the treatment of vertebral lesions (hemangioma), spreadable tumors of the spine (e.g. cancer), and osteoporotic vertebral fracture.

[0003] When performing vertebroplasty, the clinician uses fluoroscopy for needle placement and for monitoring the injection of bone cement within the vertebral body. Using a simple syringe, the clinician is exposed to excessive x-ray radiation within a fluoro field produced by a fluoroscope. It is well known that excessive exposure to x-ray radiation is dangerous and even cancer-causing. Thus, in order to reduce such exposure, the clinician should perform this procedure outside the range of the fluoro field.

[0004] Known techniques for keeping the clinician outside of the fluoro field typically involve the use of a long extension tube, whereby one end of the tube extends from an injection pump and the other end is coupled to a hollow bone needle. The extension tube is used as a conduit for delivering the bone cement from the pump to the bone needle for injection into the vertebral body. The additional length of the extension tube allows a clinician to perform the vertebroplasty at a distance outside the fluoro field.

[0005] A disadvantage of such injection devices is that the extension tube produces a pressure drop, making it more difficult to deliver the bone cement through the tube. Mechanisms can be implemented to increase the pressure for pushing the cement through the tube. However, such mechanisms typically reduce the natural feedback or "feel" of the injection device, resulting in a number of pressure concerns. For example, the lack of natural feedback can cause the clinician to inadvertently leak bone cement into the surrounding tissue or the spinal cord itself, resulting in a number of serious health risks. Furthermore, the additional length of the tube makes such injection devices susceptible to premature curing or hardening, resulting in the tube becoming clogged.

[0006] The present invention is as claimed in the claims.

SUMMARY OF THE INVENTION

[0007] The present invention is directed to a device for remotely injecting a fluorescent probe material into a patient. The fluorescent probe material can include, for example, a mixture of a bone cement (e.g., PMMA) and a fluorescent probe (e.g., barium, tantalum). Embodiments of the invention include a pump defining an injection chamber having an exit opening, an actuator, and a cable. Although not so limited, the cable can be a lensile flexible cable or a rigid rod. The cable has a first end coupled to the actuator and a second end engaging the pump. The actuator controls the pump by responsive movement of the cable, causing injection of the fluorescent probe material from the injection chamber through the exit opening into the patient.

[0008] Particular embodiments of the invention include a pump, having a piston disposed within an inner surface of the injection chamber and a piston driver engaging the piston to allow axial movement of the piston along a first axis defined by first and second end portions of the injection chamber. The second end of the cable engages the piston driver such that the actuator can control the piston driver by responsive movement of the cable, thereby causing axial movement of the piston toward the exit opening of the injection chamber. The piston driver can include gear and pulley mechanisms. The piston driver can also include a lever, thereby providing a mechanical advantage in applying a force to the piston. In alternative embodiments, the piston driver may also include hydraulic cylinders or air cylinders.

[0009] In operation, an injection pump is anchored to the patient and a hollow bone needle extends from the exit opening of the pump for transferring the fluorescent probe material into the vertebral body of the patient. The needle can be straight or angled. By anchoring the pump directly to the patient, problems typically associated with extension tubes are eliminated.

[0010] Such embodiments improve clinician safety because the pump is remotely operated at a safe distance outside the range of the fluoro field. Furthermore, the pump can be anchored directly to the patient, thereby avoiding the use of extension tubes and thereby improving control and reducing pressure concerns.

45 BRIEF DESCRIPTION OF THE DRAWINGS**[0011]**

50 FIG. 1A is a diagram illustrating a general prior art procedure for performing vertebroplasty.

FIG. 1B is a representation of a prior art device for injecting a fluorescent probe material into a patient during vertebroplasty.

FIG. 2 is a diagram of a remotely-activated vertebroplasty injection device according to one embodiment of the invention.

FIG. 3 is a detailed schematic diagram of a remote-

ly-activated injection device according to another embodiment of the invention.

FIG. 4 is a diagram illustrating an arrangement of the actuator and the cable according to the embodiment of the invention of FIG. 3.

FIG. 5 is a schematic diagram illustrating a piston driver according to another alternative embodiment of the invention.

FIG. 6 is a detailed schematic diagram of a remotely-activated vertebroplasty injection device according to still another alternative embodiment of the invention.

FIG. 7 is a schematic diagram illustrating the anchor according to one embodiment of the invention.

FIG. 8A is a diagram illustrating a remotely-activated vertebroplasty injection device according to a further alternative embodiment.

FIG. 8B is a diagram illustrating the piston driver of FIG. 8A in more detail according to one embodiment.

DETAILED DESCRIPTION OF THE INVENTION

[0012] The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The same number present in different drawings refers to the same item. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

[0013] FIG. 1A is a diagram illustrating a general procedure for performing vertebroplasty. In this procedure, anesthetized patient 1 lies on operating table 20 in a downward-facing, horizontal position underneath x-ray machine 30, referred to as a fluoroscope.

[0014] The clinician mixes the bone cement along with a fluorescent probe to the consistency of a thin paste and prepares the resulting fluorescent probe material for injection into the vertebral body through syringe 40, which is also shown in FIG. 1B. Fluorescent probe material 42 can be barium, tantalum or other injectable substance that is visible under fluoroscopy. With fluoroscopy, the clinician is able to view the fluorescent probe as it is injected into the patient and thereby control the injection process.

[0015] Fluoroscopy is a technique for obtaining "live" x-ray images of a patient. X-rays 35, represented in FIG. 1A, are transmitted from fluoroscope 30 through patient 1, striking a fluorescent plate. The fluorescent plate is coupled to an image intensifier, which is further coupled to a video camera. The camera, in turn, provides a live video feed to video monitor 50, highlighting the fluorescent probe within patient 1.

[0016] Using video monitor 50 as a visual guide, the clinician positions hollow bone needle 44, shown in FIG.

1B, into the vertebral body in the patient's back and proceeds to inject the fluorescent material. After injecting the bone cement, the cement hardens resulting in the stabilization of the vertebral body.

[0017] FIG. 2 is a diagram of a remotely-activated vertebroplasty injection device according to one embodiment of the invention. Injection device 10 includes injection pump 100 that is coupled to actuator 200 by cable 300 having a sufficient length to allow a clinician to operate pump 100 at a distance outside the range of the harmful fluoro field. For example, the cable can have a length of between about one (1) foot and about ten (10) feet, preferably at least two (2) feet, more preferably at least five (5) feet. Actuator 200 controls pump 100 by triggering 202, which causes responsive movement of cable 300, thereby injecting the fluorescent probe material from pump 100 through exit opening 106.

[0018] In operation, injection pump 100 is anchored to the patient and a hollow bone needle (not shown) extends from exit opening 106 of pump 100 for transferring the fluorescent probe material into the vertebral body of the patient. By anchoring pump 100 directly to the patient, problems typically associated with extension tubes are eliminated.

[0019] Remotely-activated injection device 10 can optionally include reservoir 400 for mixing bone cement (e.g., PMMA) and fluorescent probe (e.g., barium, tantalum) and for supplying the resulting fluorescent probe material to the injection chamber of injection pump 100.

[0020] A suitable reservoir for use with the present invention is described in US-2002/0156483-A1 published 24 October 2002, namely a device for mixing and injecting bone cement which comprises:

- 35 a) a reservoir having an exit opening and first and second ends defining a reservoir axis,
- 40 b) a first member having a mixing shank extending therefrom, the shank being disposed within the reservoir,
- 45 c) an injection chamber comprising a sterile tubular inner surface forming entry and exit openings, the exit opening of the reservoir and the entry opening of the sterile inner surface of the injection chamber being in fluid communication therebetween,
- 50 d) a plunger slidably received in an opening in the tubular inner surface of the chamber, the plunger comprising i) a piston having an inner face and an outer face, and ii) a plunger rod having first and second ends, the inner face of the piston facing the exit opening of the injection chamber and being in sealing engagement with the inner surface of the injection chamber, the outer face of the piston being attached to the first end of the plunger rod, and
- 55 e) a lever having first and second ends, the first end of the lever being pivotally attached to the device, the second end of the lever being attached to the second end of the plunger rod.

[0021] FIG. 3 is a detailed schematic diagram of a remotely-activated injection device according to another embodiment of the invention. In this embodiment, pump 100 defines injection chamber 108 having exit opening 106. Piston 110 is disposed within an inner surface of injection chamber 108 for applying a force against the fluorescent probe material in order to push the material from the injection chamber through exit opening 106.

[0022] Piston driver 120 engages piston 110 to allow axial movement of the piston along an axis defined by the end portions of injection chamber 108 toward exit opening 106. The second end of flexible cable 300 engages piston driver 120 allowing actuator 200 to control piston driver 120 by responsive movements of cable 300. In particular, the clinician operates actuator 200 at a safe distance outside the range of the harmful fluorescent field.

[0023] In the illustrated embodiment, piston driver 120 is a gear mechanism, which includes wheel 125 having a perimeter of teeth. Wheel 125 engages the teeth of two diametrically opposing elements 123, 127. Element 127 has one end mounted to an outer surface of piston 110 that is external to injection chamber 108, while element 123 has one end coupled to the engaging end of cable 300.

[0024] When actuator 200 is engaged, causing a responsive movement of the cable away from pump 100, element 123 engages wheel 125 causing a rotational movement. This rotational movement in turn causes wheel 125 to engage element 127, causing piston 110 to move axially along the inner surface of injection chamber 108 toward exit opening 106. As piston 110 moves, a force is exerted against the fluorescent probe material, thereby pushing the material through exit opening 106, where it is transferred to the patient through hollow bone needle 600.

[0025] FIG. 4 is a diagram illustrating an arrangement of the actuator and the cable according to one embodiment. In the illustrated embodiment, actuator 200 includes lever 202 pivotally-coupled to handheld base 204. In particular, lever portion 202a is pivotally-coupled to the base at base portion 204a, allowing lever 202 to move radially from a steady state position toward base 204. Lever portion 202b, in turn, is coupled to one end of cable 300. By gripping lever 202 toward base 204, lever portion 202b moves radially within base 204, thereby causing responsive movement of cable 300. The responsive movement of cable 300 engages pump 100 causing the injection of the fluorescent material into the patient.

[0026] Return spring 206 can be employed to cause lever 202 to return back to its original position as the grip on the lever is released. Actuator 200 can also include locking switch 208 for locking the radial position of lever 202, thereby preventing further responsive movement of cable 300. Base 204 can also include indicator 210 which relates the radial position of lever 202 to the volume of material injected into the patient (e.g., zero to 10

cc). Actuator 200 can be implemented in a variety of ways known to those skilled in the art to enable responsive movements of a cable.

[0027] In the illustrated embodiment, cable 300 is a tension cable. Semi-rigid housing 302 is coupled to actuator 200 by connector 304. Cable 300 is fed through housing 302 into actuator 200 where it is coupled to lever portion 202b. According to one embodiment, the cable is fed through a hole in lever portion 202b and held in place by knob 308. Thus, as lever portion 202b radially moves within base 204, cable 300 moves in response. The cable can also be implemented using a variety of cable types known to those skilled in the art for engaging a piston driver.

[0028] FIG. 5 is a schematic diagram illustrating a piston driver according to another alternative embodiment of the invention. In this embodiment, the piston driver is a pulley mechanism, including at least three pulley wheels 130, 132, and 134 positioned relative to piston 110. For example, pulley wheels 130 and 134 are mounted on opposing sides of piston 110, and pulley wheel 132 is positioned at the head end of piston 110a that is external to injection chamber 108. Cable 300 is fed through the pulley mechanism, such that a force 25 from the cable can be applied to pulley wheel 132 in the direction of the head end of piston 110a. For example, when actuator 200 causes responsive movement of cable 300 away from pump 100, cable 300 exerts a force against pulley wheel 132 pushing it against the head end of piston 110a. This allows piston 110 to move axially within injection chamber 108 toward exit opening 106, resulting in the injection of the fluorescent probe material.

[0029] The fluorescent probe material can be supplied to injection chamber 108 from reservoir 400 through opening 109, as shown, which may be as described in the above-mentioned US application US-2002/0156483-A1, in which some useful arrangements are described as follows.

[0030] In some embodiments, when a force is applied to the lever [150] in a direction parallel to plunger rod, the forward action of the piston begins at position A and ends at position B, thereby displacing an amount of bone cement equal to the traversed volume through the exit opening. However, since the piston of this embodiment does not pass over the entry opening of the injection chamber, at no time in the stroke does this piston prevent fluid communication between the reservoir and injection chamber, and so the pressure is determined by the pressure of the fluid in reservoir (which is typically low). Therefore, in some embodiments, a valve is provided between the entry opening of the sterile inner surface of the injection chamber and the exit opening of the reservoir for restricting the fluid communication therebetween. When this valve is in an open position, bone cement may be delivered from the reservoir into the injection chamber. After such delivery, valve is adjusted to its closed position, and the bone cement in the injec-

tion chamber is now in fluid isolation. Accordingly, the pressure experienced by the cement is now a function of the diameter of the inner face of piston of the injection chamber, and so the isolated cement may be more easily pressurized to a usefully high pressure by the forward action of the lever.

Although such a valve is useful in enhancing the pressure of the bone cement in the injection chamber, it nonetheless requires extra effort to open and shut the valve with each stroke. In more preferred embodiments, the stroke of the plunger is such that the piston of the plunger begins to stroke at position A (thereby allowing fluid communication between the entry and exit openings), and then moves forward across the entry opening during the injection stroke to position B₂, thereby occluding the entry opening, and preventing the fluid communication with the reservoir. Since the bone cement in the injection chamber is now in fluid isolation, the pressure experienced by the cement is now a function of the diameter of the inner face of the injection chamber piston and so may be more easily pressurized to a usefully high pressure by the forward action of the lever."

[0030] FIG. 6 is a detailed schematic diagram of a remotely-activated vertebroplasty/injection device according to still another alternative embodiment of the Invention. In this embodiment, pump 100 includes lever 150, which provides a mechanical advantage in engaging a plunger. The plunger includes shaft 152 mounted to an outer surface of piston 110 that is external to injection chamber 108 which may be as generally described in US-A-2002/0156483. In particular, in preferred embodiment, the length of plunger is such that the inner face of the piston has an initial position adjacent the entry opening of the injection chamber. When the inner face is so positioned, the only portion of the stroke in which fluid communication still exists is that small portion in which inner face passes over entry opening. Therefore, this embodiment has the advantage that virtually the entire stroke is at a high pressure. Preferably, the depth of the piston is greater than the distance between entry opening and exit opening. This condition prevents cement from flowing from the reservoir into the area of the injection chamber behind the piston.

[0031] In one preferred embodiment, now referring to Fig. 2c, the length of plunger rod is such that the inner face of the piston has a final position B₂ substantially adjacent the exit opening of the injection chamber. In this mode, the plunger movement completely empties the chamber of bone cement. This has the advantage of providing more ejection volume per stroke, thereby requiring fewer strokes to deliver a predetermined volume.

[0032] To remotely activate injection pump 100, the cable coupling injection pump 100 to actuator 200 is rigid rod 310. In particular, one end of rod 310 is attached to the lever, while the other end engages actuator 200. In this embodiment, actuator 200 can be implemented using a ratchet and pawl design, in which the actuator

causes rod 310 to move toward lever 150 when the trigger (i.e., ratchet) is applied and engages teeth 315 of rod 310 (i.e., pawl).

[0033] As rod 310 pushes against lever 150, a force is exerted against shaft 152, which is attached to piston 110. Thus, the applied force allows piston 110 to move axially in injection chamber 108 toward exit opening 106, through which the fluorescent material is injected. Return spring 154 can be employed to return lever 150 back to its original position as rod 310 is retracted back to actuator 300.

[0034] As shown in FIGS. 3 and 5, bone needle 600 is inserted through anchor 500, which mounts injection pump 100 to patient 10. The bone need can be straight as shown or bent at a angle (e.g., 90 degrees) in order to remove the pump outside of the fluoro field. Anchor 500 fixes the positioning of the bone needle within the vertebral body, preventing further movement. By anchoring the pump to the patient, the need for an extension tube is avoided, allowing for greater control and reduced pressure concerns.

[0035] FIG. 7 is a schematic diagram illustrating the anchor according to one embodiment. In some embodiments, the anchors that are used are disclosed in U.S. Patent Application Serial No. 10/259,689, entitled "Novel Device for Advancing a Functional Element, filed on September 30, 2002.

[0036] FIG. 8A is a diagram illustrating a remotely-activated vertebroplasty injection device according to a further alternative embodiment. In this embodiment, the pump includes a housing 180 which is attached to the patient using an adhesive pad 182. The housing 180 includes a funnel-shaped exit 170, which is coupled to flexible tubing 174. The flexible tubing 174 is further coupled to a bone needle 600 by a needle coupler 176. The housing 180 includes a injection chamber, referred to as cement chamber 108, in which a piston 182 moves axially within the chamber. In the illustrated embodiment, the piston 182 moves vertically toward the funnel-shaped exit 172.

[0037] The piston 182 is engaged by a piston driver 184 (shown in more detail in FIG. 8B) to allow axial movement of the piston. A cable 300 is fed into the housing 180 through a cable housing 302. The engaging end of the cable 300 engages the piston driver 184 to control the movement of the piston 182.

[0038] In particular, the actuator (not shown) controls the piston driver 184 by responsive movement of the cable 300 to cause axial movement of the piston toward the funnel-shaped exit 172 of the chamber 108. As the piston moves vertically, the fluorescent probe cement is forced up into the funnel-shaped exit 172, through flexible tubing 174, and into the needle coupler 176 for injection into the vertebral body of the patient through the bone needle 600.

[0039] FIG. 8B is a diagram illustrating the piston driver of FIG. 8A in more detail according to one embodiment. The piston driver 184 includes a screw shaft 170

having one end mounted to a surface of the piston 182, external to the cement chamber 108. The opposite end of the shaft 170 is positioned through the open centers of gear wheels 166 and 168, each having a perimeter of teeth. The engaging end of cable 300 is attached to an element 164 having teeth which can engage either one of the gear wheels 166, 168. When the actuator (not shown) causes a responsive movement away from the pump, the responsive movement causes a rotational movement of the gear wheel 166, 168, which further causes the screw shaft 170 to move in an upward direction toward the cement chamber 108. As the shaft 170 moves, the piston 182 moves in conjunction toward the funnel-shaped exit 172, forcing the material out of the chamber 108. According to one embodiment, the gear wheels 166 and 168 can have different diameters. Thus, the fluorescent probe material (e.g., fluorescent bone cement) can be injected at different rates.

[0040] In some embodiments, the vertebral body is first prepared by lavage to create a porous matrix suitable for accepting the cement under low pressure. In some embodiments, the lavage procedures that are used are disclosed in U.S. Patent Application Serial No. 10/301,451, entitled "Methods of Performing Embolism-Free Vertebroplasty and Devices Therefor," filed November 21, 2002.

[0041] In some embodiments, the cements are osteobiologic. In some embodiments, the osteobiologic compositions that are used are disclosed in U.S. Provisional Patent Application Serial No. 60/448,221, entitled "Omnibus In-Situ Formed Intervertebral Fusion Device," filed February 14, 2003.

EQUIVALENTS

[0042] While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details can be made therein without departing from the scope of the invention which is as claimed in the appended claims

Claims

1. A device that injects a fluorescent probe material into a patient, comprising:

a pump defining an injection chamber having an exit opening;
an actuator; and
a cable having a first end coupled to the actuator, and a second end engaging the pump, whereby the actuator controls the pump by responsive movement of the cable to thereby cause injection of a fluorescent probe material from the injection chamber of the pump through the exit opening to the patient.

2. The device of Claim 1 wherein the actuator comprises:

a base; and
a lever having a first end portion pivotally-connected to the base, and a second end portion coupled to the first end of the cable, whereby pivotal movements of the lever cause responsive movement of the cable.

3. The device of Claim 1 wherein the pump comprises:

a piston disposed within an inner surface of the injection chamber;
a piston driver engaging the piston to allow axial movement of the piston along a first axis defined by first and second end portions of the injection chamber;
the second end of the cable engaging the piston driver; and
the actuator controlling the piston driver by responsive movement of the cable to thereby cause axial movement of the piston toward the exit opening of the injection chamber, thereby further causing injection of the fluorescent probe material through the exit opening.

4. The device of Claim 3 wherein the piston driver includes a gear mechanism.

5. The device of Claim 4 wherein the gear mechanism comprises:

a wheel having a perimeter of teeth, the wheel engaging first and second opposing elements; the first opposing element having an end mounted to the piston;
the second opposing element having an end coupled to the second end of the cable, whereby responsive movement of the cable causes axial movement of the second element, thereby causing rotational movement of the wheel, thereby further causing axial movement of the first element and the piston toward the exit opening of the injection chamber.

6. The device of Claim 3 wherein the piston driver includes a pulley mechanism.

7. The device of Claim 6 wherein the pulley mechanism comprises:

at least three pulley wheels, whereby a first pulley wheel of the at least three pulley wheels is positioned at a head end of the piston;
the at least three pulley wheels engaged by the second end of the cable such that the responsive movement of the cable causes the first pul-

ley wheel to exert a force against the piston, thereby causing axial movement of the piston toward the exit opening of the injection chamber.

8. The device of Claim 1, wherein the cable is a rigid rod.

9. The device of Claim 8, wherein the pump comprises:
a piston disposed within an inner surface of the injection chamber, the piston having an outer surface;
a shaft having a first end and a second end, the first end of the shaft being mounted to the outer surface of the piston;
a lever having first and second ends, the first end of the lever being pivotally-connected to the pump, the second end of the lever positioned to bear upon the second end of the shaft; the second end of the rigid rod coupled to the lever;
the actuator controlling the lever by responsive movement of the rigid rod to cause the lever to exert a force upon the second end of the shaft, thereby causing axial movement of the piston toward the exit opening of the injection chamber, thereby further causing injection of the fluorescent probe material through the exit opening.

10. The device of Claim 1, further comprising an anchor coupling the pump to a patient.

11. The device of Claim 10, further comprising:
a needle coupled to the exit opening in the second end portion of the injection chamber, and the needle being guided to the patient through the anchor.

12. The device of Claim 11, wherein the needle is angled.

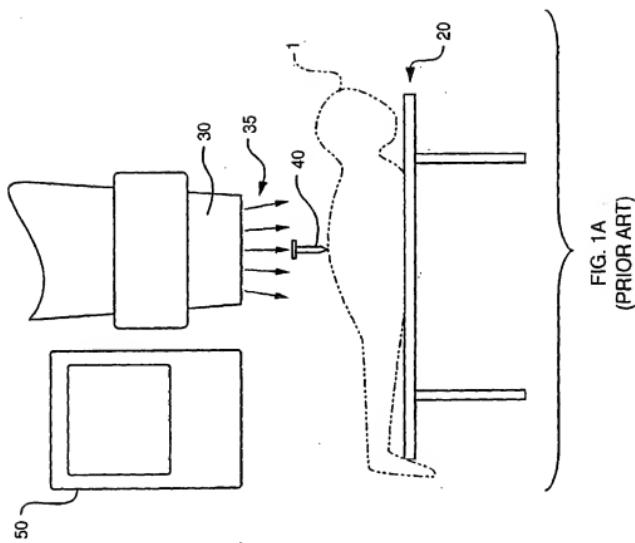
13. The device of Claim 1, further comprising:
a fluorescent probe material in the injection chamber.

14. The device of Claim 1, wherein the fluorescent probe material is a mixture of a bone cement and a fluorescent probe.

15. The device of Claim 1, wherein the fluorescent probe material comprises barium

16. The device of Claim 1, wherein the fluorescent probe material comprises tantalum.

17. A method of delivering a material into a patient having a vertebral body, comprising the steps of
a) removing soft tissue from the vertebral body to create a skeleton having open porosity;
b) anchoring the device of claim 1 to the patient; and
c) delivering a hardenable material into the open porosity of the vertebral body.



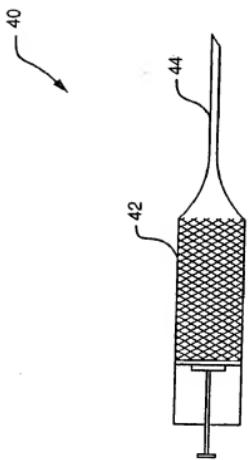


FIG. 1B
(PRIOR ART)

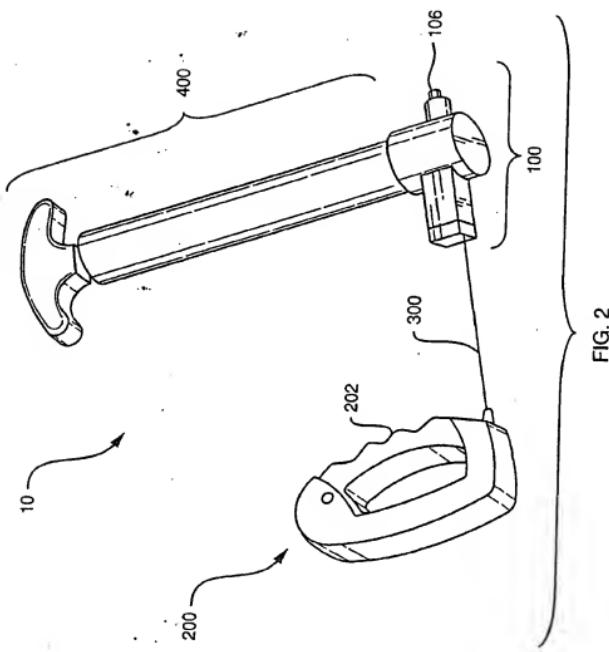


FIG. 2

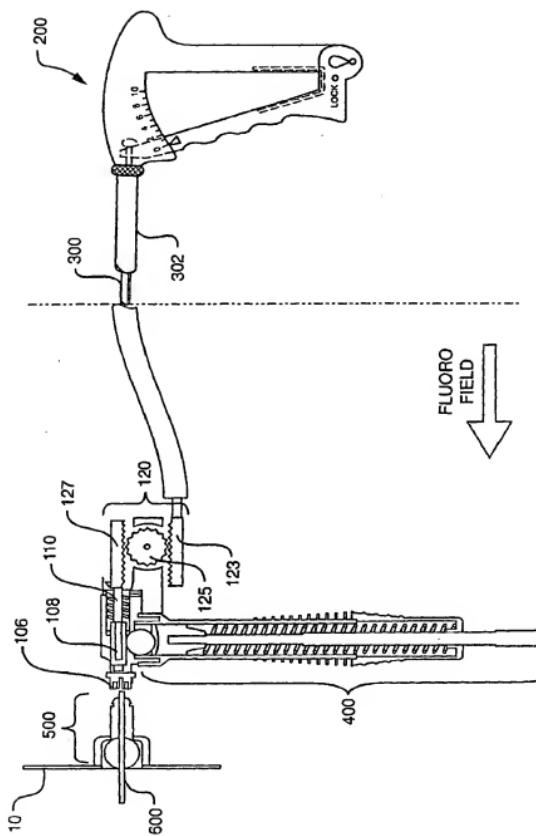


FIG. 3

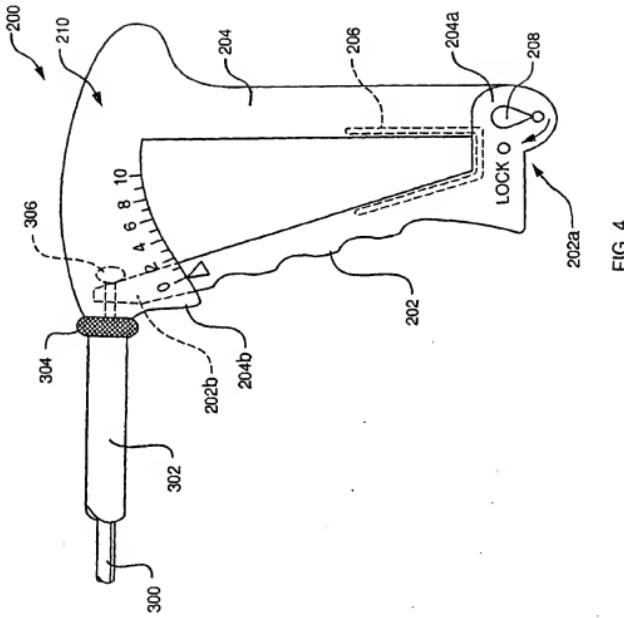


FIG. 4

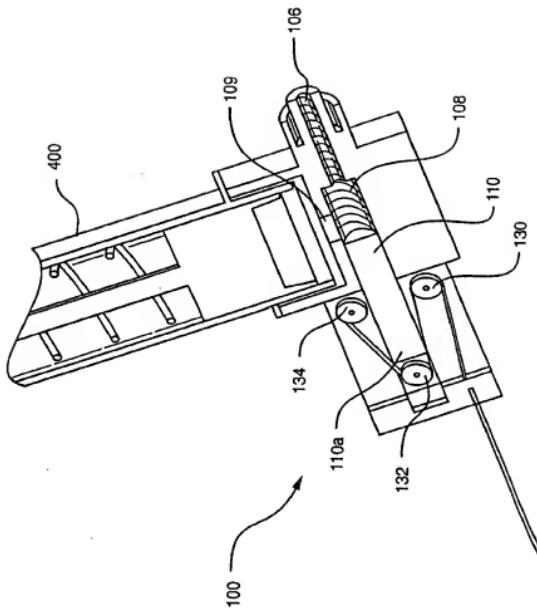


FIG. 5

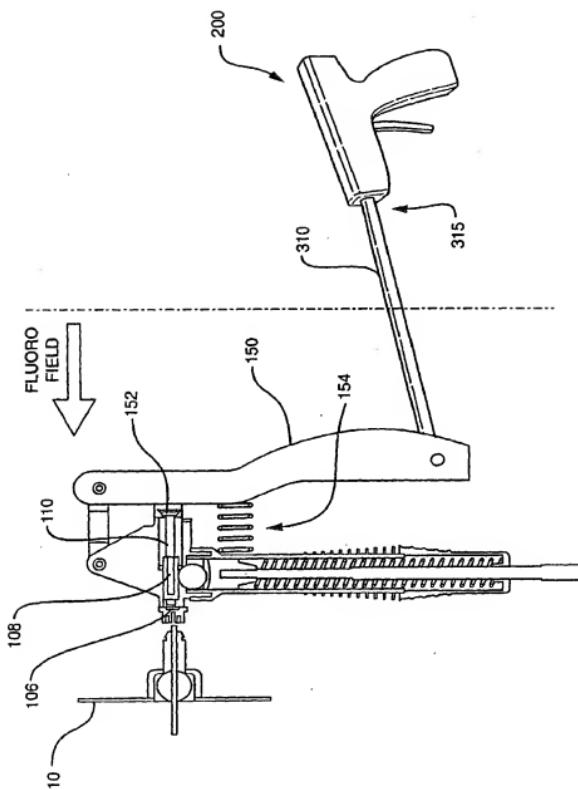


FIG. 6

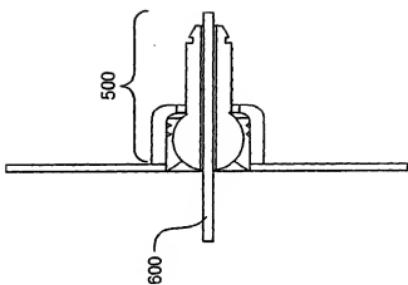


FIG. 7

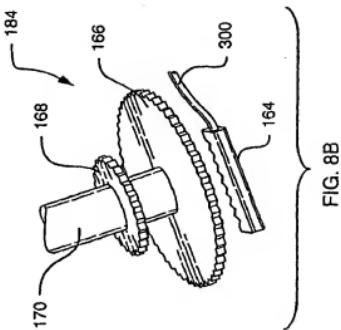


FIG. 8B

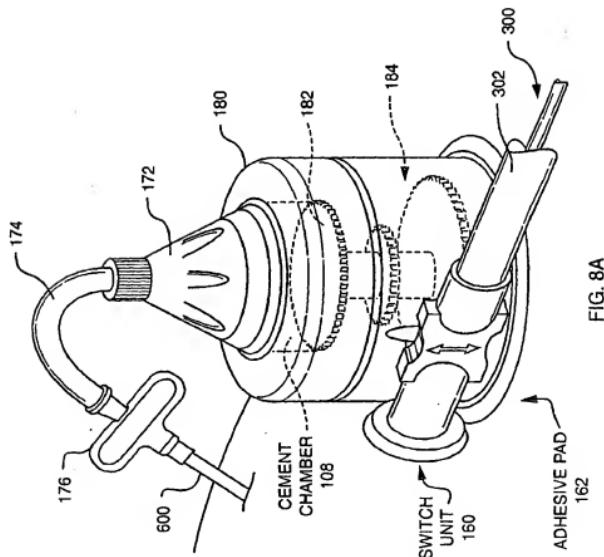


FIG. 8A



European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 04 25 1929
shall be considered, for the purposes of subsequent
proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	US 2002/177866 A1 (WEIKEL STUART ET AL) 28 November 2002 (2002-11-28) * abstract; figure 1 -----	1	A61B17/58 A61F2/46
A	US 2003/050702 A1 (BERGER J-LEE) 13 March 2003 (2003-03-13) * abstract; figure 1 -----	1	
A	US 6 309 420 B1 (PREISSMAN HOWARD) 30 October 2001 (2001-10-30) * abstract * -----	1	
A	WO 01/13822 A (SPINEOLOGY INC) 1 March 2001 (2001-03-01) * abstract * -----	1	
A	WO 03/097854 A (KUSLICH STEPHEN D ; GLEASON JOSEPH E (US); PETERSON FRANCIS (US); SPIN) 30 January 2003 (2003-01-30) * abstract; figures 2,8 * -----	1	
P,A	WO 2004/002375 A (FACCIOLO GIOVANNI ; SOFFIATTI RENZO (IT); TECRES SPA (IT)) 8 January 2004 (2004-01-08) * abstract; figure 1 -----	1	
INCOMPLETE SEARCH			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
<p>The Search Division considers that the present application, or one or more of its claims, does/do not comply with Rule 5(2) to the extent that a meaningful search into the state of the art cannot be carried out, or cannot be carried out partially, for these claims.</p> <p>Claims searched completely :</p> <p>Claims searched incompletely :</p> <p>Claims not searched :</p> <p>Reason for the limitation of the search: See sheet C</p>			
Place of search	Date of completion of the search	Examiner	
Berlin	21 July 2004	Nielsen, M	
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background C : non-written disclosure P : intermediate document</p> <p>E : theory or principle underlying the invention F : embodiment of the invention, but published on, or after the filing date D : document cited for the reasons L : document cited for other reasons B : member of the same patent family, corresponding document</p>			



Claim(s) searched completely:
1-16

Claim(s) not searched:
17

Reason for the limitation of the search (non-patentable invention(s)):

Article 52 (4) EPC - Method for treatment of the human or animal body by
surgery

ANNEX TO THE EUROPEAN SEARCH REPORT
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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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